



Food and Drug Administration
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March 12, 2015

Biomet Spine, LLC
Mr. Mike Medina
Director, Regulatory Affairs
310 Interlocken Parkway, Suite 120
Broomfield, Colorado 80021

Re: K142634
Trade/Device Name: Biomet Spine Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: February 6, 2015
Received: February 9, 2015

Dear Mr. Medina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142634

Device Name

Biomet Spine Fusion System

Indications for Use (Describe)

When used as a lumbar intervertebral body fusion device, the Biomet Spine Fusion System ("Biomet Spine Fusion System") is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Biomet Spine Fusion System is to be implanted via an anterior or posterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Biomet Spine Spinal Fixation System. The expandable interbody fusion devices are not indicated for vertebral body replacement

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date:	February 4, 2015
Applicant/Sponsor:	Biomet Spine LLC. 310 Interlocken Parkway, Suite 120 Broomfield, CO 80021
Contact Person:	Mike Medina Director, Regulatory Affairs Phone: 303-501-8548 Fax: 303-501-8444
Trade Name:	Biomet Spine Fusion System
Common Name:	Intervertebral Body Fusion Device, Lumbar
Device Class:	Class II
Classification Name (Product Code):	Intervertebral body fusion device MAX
Device Panel – Regulation No.:	Orthopedic – 21 CFR 888.3080
Primary Predicate:	Spinal Elements Lucent K081968
Additional Predicates:	Biomet Spine Fusion System K083815, Medtronic/AMT Wave K083626, Globus Medical Caliber K102293

Device Description & Technological Characteristics:

The Biomet Spine Fusion System implants are intervertebral body fusion/vertebral body replacement devices consisting of a rectangular or semi-rectangular shape and various heights and footprints. The devices have a hollowed out central area to accommodate bone graft. The upper and lower surfaces of the devices have a series of transverse grooves formed to improve stability and fixation once the device is inserted. The implants are available in a variety of sizes and configurations to approximate anatomical variation in different vertebral levels and/or patient anatomy. The implants are made of PEEK (OPTIMA LT1®) per ASTM F2026, titanium alloy (Ti-6Al-4V ELI) per ASTM F136, commercially pure titanium per ASTM F1580, and may include tantalum markers per ASTM F560. The expandable Biomet Spine Fusion System implants incorporate PEEK (OPTIMA LT1® per ASTM F2026) spacer components and titanium alloy (Ti-6Al-4V ELI per ASTM F136) endplate components that orient into predetermined lordotic angles of 0, 8 and 12 degrees. The expandable implants are available in 7 to 14mm heights, an 11mm width, and 25, 30 and 35mm lengths. The Biomet Spine Fusion System is intended to be sterile.

Intended Use / Indications for Use:

When used as a lumbar intervertebral body fusion device, the Biomet Spine Intervertebral Body Fusion System (“Biomet Spine Fusion System”) is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease (“DDD”) at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Biomet Spine Fusion System is to be implanted via an anterior or posterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Biomet Spine Spinal Fixation System. The expandable interbody fusion devices are not indicated for vertebral body replacement.

Summary of Technologies:

The technological characteristics of the subject Biomet Spine Fusion System components remain the same as, or similar to, the predicate devices in regards to intended use, indications for use, design, materials, manufacturing methods, fundamental technology, and operational principles.

Performance Data:

Mechanical testing was conducted in accordance with FDA's Guidance for Industry and FDA Staff – Spinal System 510(k)s dated May 3, 2004 and Class II Special Controls Guidance Document: Intervertebral Body Fusion Device dated June 12, 2007. Performance testing was performed to demonstrate substantial equivalence to the predicate device(s). Performance testing included tests per ASTM F2077 (static and dynamic axial compression, static and dynamic shear compression, and static torsion), ASTM F2267 (subsidence) and particulate wear analysis per ASTM F1877. In all instances, the modified device met or exceeded predicate device performance, functioned as intended and therefore demonstrated substantial equivalence to the predicate device(s).

Substantial Equivalence:

The modified Biomet Spine Fusion System implants included in the product line extension have the same intended use, indications, technological characteristics, and principles of operation as the previously cleared Biomet Spine Fusion System (K083815), Spinal Elements Lucent (K081968, K122967), AMT, Inc./Medtronic Wave (K083626) and Globus Medical Caliber (K102293). The minor differences in the new components do not raise any new issues of safety or effectiveness. Performance data presented also demonstrated comparable properties to the previously cleared devices.

Conclusion:

The Biomet Spine Fusion System is substantially equivalent to the predicate systems as a spinal fusion device in regards to intended use, indications for use, fundamental technology including design, materials, manufacturing methods, sterility, and operational principles.

Furthermore, mechanical testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject components to the Biomet Spine Fusion System to the predicate system. Based on this information, the subject modifications do not raise any new issues regarding the safety or efficacy when compared to its predicates.